

# **Mexican Wolf Blue Range Reintroduction Project**

## **Adaptive Management Oversight Committee**

### **Standard Operating Procedure**

**Title:** Requirements for Pharmaceutical Storage, Access, and Record Keeping

**Number:** 20.0

**File Name:** MW SOP 20.Requirements for Pharmaceuticals.Final.20050430.doc

**Purpose:** This SOP establishes the requirements for storage, access, and use of pharmaceuticals provided or permitted by USFWS. Use of any pharmaceuticals provided by, or used pursuant to permits issued or held by, other cooperating agencies are subject to the provisions and constraints established by the appropriate cooperating agency. This SOP supersedes relevant sections of the 1998 Mexican Wolf Interagency Management Plan (USFWS 1998), and therefore represents, in part, the “Service Approved Management Plan” referenced in the Mexican Wolf Final Rule (50 CFR 17.84(k)).

**Exceptions:** Because of the legal requirements required under state and federal law for tracking pharmaceutical use, there are no exceptions to this SOP. Any deviation will require prior revision of this SOP, in accordance with SOP 2.0.

**Background:** Pharmaceuticals are often used for health maintenance, care, and handling (e.g. vaccines, antibiotics, anesthetics) of Mexican wolves. Some of these pharmaceuticals are federally classified as controlled substances, the use of which is regulated by the Drug Enforcement Administration (DEA) and state agencies to prevent diversion for illicit purposes. Proper storage of pharmaceuticals and documentation of use ensures that state and federal regulations are being met. This SOP does not supersede any state or federal policies or laws, but provides guidelines and defines appropriate actions that will allow the USFWS Mexican Wolf Recovery Program to comply with provisions of the Animal Medicinal Drug Use Clarification Act, and provide appropriate pharmaceuticals to the Reintroduction Project.

Pharmaceuticals controlled by the DEA may only be purchased and dispensed by persons currently licensed by the DEA. Dr. David Hunter, veterinarian for the Turner Endangered Species Fund (TESF; one of several formal cooperators with the USFWS Mexican Wolf Recovery Program.), is licensed by the DEA and has agreed to provide various pharmaceuticals to the Mexican Wolf Recovery Program, provided he has the necessary oversight to meet his ethical and legal responsibilities. Dr. Hunter has approved this SOP (see Approvals, below), and strict compliance by all IFT members or other individuals assisting the IFT is mandatory.

#### **Procedures:**

1. Use of pharmaceuticals provided by USFWS for the Mexican Wolf Recovery Program (including the Reintroduction Project) is subject to the direction of licensed veterinarian Dr. David Hunter, through his formal relationship with USFWS. While IFT personnel may be licensed for use of pharmaceuticals through their employer, and/or for uses in other situations,

all use of pharmaceuticals provided by USFWS through Dr. Hunter is considered a federal action under the direction of Dr. David Hunter.

2. The standards listed below (Procedure 3 et seq.) are minimum criteria for all IFT members. Project personnel may also have more stringent agency-specific requirements regarding use of pharmaceuticals that require additional measures to be taken. This SOP in no way exempts or supersedes any agency-specific standards for use, handling, and storage of pharmaceuticals by that agency's employees.
3. Controlled substance storage.
  - a. Security
    - i. All controlled substances will be stored in securely locked cabinets, safes, or refrigerators. Biologists using controlled substances in the field are not required to meet this storage requirement, but are required to ensure that all drugs are protected and secured by the best means available to prevent damage, accidental human exposure, or theft.
    - ii. All controlled substances will be maintained in possession of authorized biologists after removal from storage.
    - iii. Controlled substances will not be left in unattended vehicles.
  - b. Types of storage.
    - i. Inventory storage: Consists of all pharmaceuticals that are being stored until transferred to the ready supply.
    - ii. Ready supply: Consists of pharmaceuticals currently available for use or those supplies that can reasonably be expected to be needed in the immediate future.
  - c. Location of Inventory and Ready supply of pharmaceuticals.
    - i. Regional Office: Albuquerque, NM.
    - ii. Field Office: Alpine, AZ
4. Personnel.
  - a. Training:
    - i. All personnel using pharmaceuticals are required to complete initial and yearly training regarding proper pharmaceutical handling, storage, and record keeping requirements. This training must be approved by the signing veterinarian (Dr. Hunter).
    - ii. All personnel will complete training as specified in SOP 3.0: Immobilizing and Processing a Mexican Wolf, regarding proper administration of pharmaceuticals.
    - iii. Under no circumstances will untrained or volunteer personnel be allowed to handle, administer, or possess controlled substances.
  - b. Authorized personnel by location: Only authorized personnel will have access to pharmaceuticals (Appendix A).
    - i. Regional Office:
      - (1) Inventory supply.
        - (a) Mexican Wolf Recovery Coordinator.
        - (b) Assistant Mexican Wolf Recovery Coordinator.
        - (c) David Hunter, D.V.M. or other licensed D.V.M. approved by Dr. Hunter.
      - (2) Ready supply.

- (a) Mexican Wolf Recovery Coordinator.
    - (b) Assistant Mexican Wolf Recovery Coordinator.
    - (c) David Hunter, D.V.M. or other licensed D.V.M. approved by Dr. Hunter.
    - (d) Permanent field staff meeting the requirements of this SOP and approved by the Mexican Wolf Recovery Coordinator.
  - ii. Field Office:
    - (1) Inventory supply.
      - (a) Mexican Wolf Recovery Coordinator.
      - (b) Mexican Wolf Field Projects Coordinator.
      - (c) Assistant Mexican Wolf Recovery Coordinator.
      - (d) Assistant Mexican Wolf Field Projects Coordinator.
      - (e) David Hunter, D.V.M. or other licensed D.V.M. approved by Dr. Hunter.
    - (2) Ready supply.
      - (a) Mexican Wolf Recovery Coordinator.
      - (b) Mexican Wolf Field Projects Coordinator.
      - (c) Assistant Mexican Wolf Field Projects Coordinator.
      - (d) David Hunter, D.V.M. or other licensed D.V.M. approved by Dr. Hunter.
      - (e) Permanent field staff meeting the requirements of this SOP and approved by the Mexican Wolf Recovery Coordinator.
- 5. Records.
  - a. Requirements.
    - i. Records must be readily retrievable.
    - ii. Records must be accurate and reflect current inventory.
    - iii. All records shall be made available for inspection by duly authorized officials of the Drug Enforcement Administration (DEA).
  - b. Types of records.
    - i. Inventory (Appendix B).
      - (1) Inventory must be:
        - (a) Conducted every 2 years, by personnel authorized to access the inventoried supply of controlled substances, and must include:
          - (i) Name, address, and DEA registration number.
          - (ii) Date and time of inventory.
        - (b) Signed by person(s) taking inventory.
        - (c) Be maintained at the location appearing on the registration certificate for at least 2 years.
      - (2) Separate records for Schedule II drugs. It is not anticipated that the Mexican Wolf Recovery Program will use any Schedule II drugs, therefore no inventory form is included in this SOP. Use of these drugs will require a revision of this SOP.
  - c. Pharmaceutical Tracking Form (Appendix C).
    - i. This form is to be started upon receipt of pharmaceuticals by personnel authorized to access the inventoried supply of pharmaceuticals, and completed as pharmaceuticals are used. This form will include the following information:
      - (1) Pharmaceutical name, manufacturer, lot number, concentration and expiration date.
      - (2) Date received, amount received, initials of authorized person completing form and

- the location of storage.
- (3) Date used, amount used, amount remaining, purpose and initials of person using or transferring pharmaceutical.
  - (4) Each vial of controlled substance will receive a unique nine-digit identification number upon receipt that will consist of the date received, first initial of the drug and vial number. For example, two vials of Telazol received on 7/15/02 would be labeled 071502T01 and 071502T02 respectively.
  - (5) The person transferring the controlled substance to ready supply will record the transfer on the Pharmaceutical Tracking Form and issue a Drug Tracking Record for Field Use (see Procedure 5e, below).
  - (6) Completed Drug Tracking Records for Field Use and empty vials of controlled substances are to be returned to the person authorized to access the inventoried supply of controlled substances who will then complete the Pharmaceutical Tracking Form.
  - (7) All completed forms are to be stored with the inventory supply of pharmaceuticals.
- d. Drug tracking record for field use (Appendix D).
- i. This form is to be completed by the authorized personnel using the controlled substance in the field. This form will include the following information:
    - (1) Controlled substance name, concentration, and expiration date.
    - (2) The date the form was issued and date the vial was opened.
    - (3) Vial number.
    - (4) Date, amount used, amount remaining, wolf ID number, purpose and location of use.
    - (5) Initials of person using the controlled substance.
    - (6) A Drug Tracking Record for Field Use form will be maintained for each vial of controlled drug and issued when a controlled drug is dispensed to ready supply.
    - (7) The Drug Tracking Record for Field Use form will be maintained with the dispensed vial of controlled drug until the vial is empty, outdated, or contaminated at which time the Drug Tracking Record for Field Use form and vial will be returned to personnel authorized to access the inventoried supply of pharmaceuticals.
    - (8) Each authorized person receiving controlled substances for field use is responsible for ensuring that the quantity of drug in their possession matches the quantity indicated on the Drug Tracking Record for Field Use form. Personnel should account for drug quantities when signing out a drug and upon return of the drug to the secured ready supply.
6. Theft.
- a. In case of theft or loss of controlled substances, immediately notify the Mexican Wolf Recovery Coordinator and David Hunter, D.V.M. The loss or theft of controlled substances requires a formal report to the nearest DEA field office and the local police department must be notified.
    - i. DEA field office for New Mexico: Albuquerque District Office (505) 262-6283.
    - ii. DEA field office for Arizona: Phoenix Division (602) 640-5700.

7. Disposal. Special disposal requirements apply to controlled substances. Do not dispose of any controlled substance. All expired or contaminated controlled substance drugs and unused darts still containing drugs must be turned in to the Mexican Wolf Recovery Coordinator or David Hunter D.V.M. for proper disposal procedures according to procedures outlined in Title 21 of the Code of Federal Regulations.

**Approvals:**

The Mexican Wolf Blue Range Reintroduction Project Adaptive Management Oversight Committee approved this SOP on November 23, 2004.

/s/ Dr. John Morgart  
Dr. John Morgart  
Mexican Wolf Recovery Coordinator

November 23, 2004  
Date

/s/ Dr. David Hunter  
David Hunter, D.V.M.,  
Turner Endangered Species Fund

November 23, 2004  
Date

**References:** None

## Appendix A.

### Signature Page for Inventory Supply Access

By signing below, the undersigned acknowledge the receipt of a key(s) to the Inventory Supply safe referenced in SOP 20.0 at the location(s) specified, and agree that the key(s) will only be in their own possession or loaned only to those individuals on this list, if necessary. Upon termination of employment with the Mexican Wolf Project, the undersigned agrees to return the key(s) to the Mexican Wolf Recovery Coordinator.

_____	_____	<u>  X  </u>	<u>  X  </u>
Mexican Wolf Recovery Coordinator	Date	RO key	Alpine key

_____	_____	<u>  X  </u>	<u>  X  </u>
Asst. Mexican Wolf Recovery Coordinator	Date	RO key	Alpine key

_____	_____	_____	<u>  X  </u>
Mexican Wolf Field Coordinator	Date	RO key	Alpine key

_____	_____	_____	<u>  X  </u>
Asst. Mexican Wolf Field Coordinator	Date	RO key	Alpine key

_____	_____	<u>  X  </u>	<u>  X  </u>
David Hunter, D.V.M., TESF	Date	RO key	Alpine key

**Appendix B.**

**CONTROLLED SUBSTANCE INVENTORY**

**SCHEDULE III - V**

<b>DRUG</b>	<b>CONCENTRATION</b>	<b>AMOUNT</b>

**Name:**\_\_\_\_\_

**Address:**\_\_\_\_\_

**DEA registration number:**\_\_\_\_\_

**Date:**\_\_\_\_\_

**Time of Inventory:**\_\_\_\_\_

**Person(s) Taking Inventory:**

**Signature(s):** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## Appendix C.

### PHARMACEUTICAL TRACKING FORM

Received:

Date: \_\_\_\_\_

Amount: \_\_\_\_\_

By: \_\_\_\_\_

Location:

Albuquerque ☐

Alpine ☐

Pharmaceutical:

Manufacturer:

Lot number:

Concentration:

Expiration date:

Vial number(s): \_\_\_\_\_

Date	Amount Used (ml)	Amount Remaining (ml)	Purpose	Initials



## Appendix D.

### Drug Tracking Record for Field Use

Pharmaceutical: \_\_\_\_\_

Concentration: \_\_\_\_\_

Date Issued: \_\_\_\_\_

Expiration date: \_\_\_\_\_

Vial # \_\_\_\_\_

Date vial opened: \_\_\_\_\_

Date	Amount Used (ml)	Amount Remaining (ml)	Wolf ID#, Purpose, Location	Initials